Attorney Reference Number 6395-68278-03 Express Mail Label No. EV 668293357 US Date of Deposit: July 28, 2006

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Papania et al. Application No. Not yet assigned

Filed: Herewith

Confirmation No. Not yet assigned

For: AEROSOL DELIVERY SYSTEMS AND

**METHODS** 

Examiner: Not yet assigned Art Unit: Not yet assigned

Attorney Reference No. 6395-68278-03

MAIL STOP AMENDMENT COMMISSIONER FOR PATENTS P.O. BOX 1450 ALEXANDRIA, VA 22313-1450

## PETITION TO MAKE SPECIAL BASED ON MANUFACTURE UNDER MPEP § 708.02(I)

Applicants hereby petition to make the above-referenced application special. Submitted herewith is a Statement in Support of Petition to Make Special based on Manufacture under MPEP § 708.02(I) and the petition fee under 37 C.F.R. § 1.17(h).

References deemed most closely related to the subject matter encompassed by the claims are cited on the Information Disclosure Statement (IDS) submitted concurrently with this petition. Copies of non-U.S. patent documents cited on the IDS have been provided. Copies of U.S. patent documents cited on the IDS will be provided upon request.

Please charge any additional fees that may be required in connection with filing this petition, or credit any overpayment, to Deposit Account No. 02-4550. A copy of this sheet is enclosed.

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Respectfully submitted,

Registration No. 43,652

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COMMISSIONER FOR PATENTS P.O. BOX 1450 ALEXANDRIA, VA 22313-1450

## STATEMENT IN SUPPORT OF PETITION TO MAKE SPECIAL BASED ON MANUFACTURE UNDER MPEP § 708.02, I

- 1. The Government of the United States of America as represented by the Secretary of the Department of Health and Human Services, Centers for Disease Control and Prevention (hereinafter "The Government") is an assignee of the above-referenced application, which is the U.S. national stage application of PCT/US2005/011086. An assignment of the invention to The Government has been recorded at Reel 016816, Frames 0401-0403.
- 2. The Government has granted AerovectRx Corporation (hereinafter "AerovectRx"), having a place of business at Suite 1500, 3003 Summit Blvd., Atlanta, GA, 30319, an exclusive commercialization license under the application to manufacture the invention.
- 3. AerovecRx asserts that it has sufficient capital through outside investors and facilities to manufacture the invention in quantity to be made available to AerovectRx if a patent is granted.
- 4. AerovectRx, through its authorized subcontractors, currently manufactures the invention on a small scale for use in clinical trials outside the U.S. AerovectRx will not

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manufacture the invention on a large scale for commercial sale in the U.S. unless certain that a patent will be granted on the application.

- 5. AerovectRx has obligated itself to manufacture the invention in the U.S. in quantity immediately upon the allowance of claims or issuance of a patent which will protect the investment of capital and facilities.
- 6. The Government has a good knowledge of the pertinent prior art in the field of the invention. Also, original claims 1-25 of corresponding PCT Application No.

  PCT/US2005/011086 have been searched by the European Patent Office.
- 7. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Andrew Watkins

Director, Technology Transfer Office

Centers for Disease Control and Prevention (CDC)

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